

Ignyta, Inc.
Form 8-K
August 04, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 4, 2014

IGNYTA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State of Incorporation)

001-36344
(Commission

45-3174872
(IRS Employer

File Number)
11095 Flintkote Avenue, Suite D

Identification No.)

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San Diego, California 92121

(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (858) 255-5959

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- .. Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- .. Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- .. Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- .. Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01 Entry into a Material Definitive Agreement.

On August 4, 2014, Ignyta, Inc. (the Company) entered into a license agreement (the License Agreement) with Nerviano Medical Sciences, S.r.l. (NMS) which grants the Company exclusive global rights, including the right to grant sublicenses, to develop and commercialize two drug development programs, which the Company refers to as RXDX-103 and RXDX-104. The Company's rights under the License Agreement are exclusive for the term of the License Agreement with respect to RXDX-103 and RXDX-104 and also, as to NMS, are exclusive for a five-year period with respect to any product candidate with activity against the target proteins of RXDX-103 and RXDX-104, subject to NMS's right to develop and commercialize a predecessor compound to RXDX-103 solely for animal indications.

The License Agreement provides that the Company will assume control of financial and all other responsibility for continued development of RXDX-103 immediately, and of RXDX-104 upon the earlier of December 31, 2014 or the identification of a lead development candidate. The Company is obligated under the License Agreement to use commercially reasonable efforts to develop and commercialize RXDX-103 and RXDX-104.

Under the terms of the License Agreement, the Company will make an up-front payment to NMS of \$3.5 million by August 14, 2014. When and if commercial sales of RXDX-103 or RXDX-104 begin, the Company will be obligated to pay NMS tiered royalties ranging from a mid-single digit percentage to a low double digit percentage of net sales, depending on annual amounts of net sales, with standard provisions for royalty offsets to the extent the Company is required to obtain any rights from third parties to commercialize either RXDX-103 or RXDX-104. The Company is also required to make development and regulatory milestone payments to NMS of up to \$102.0 million in the aggregate if specified clinical study initiations and regulatory approvals are achieved across multiple products or indications.

The License Agreement provides that NMS will transfer to the Company all data, technology and know-how related to RXDX-103 and RXDX-104 and necessary for their continued development. The Company's ability to continue development for RXDX-103 and RXDX-104 is dependent on that transfer process being completed successfully and in a timely manner.

The License Agreement will remain in effect until the expiration of all of the Company's royalty and sublicense revenue obligations to NMS, determined on a product-by-product and country-by-country basis, unless the Company elects to terminate the License Agreement earlier. If the Company fails to meet its obligations under the License Agreement and is unable to cure such failure within specified time periods, NMS can terminate the License Agreement, resulting in a loss of the Company's rights to RXDX-103 and RXDX-104.

The foregoing description of the License Agreement is qualified in its entirety by reference to the full text of the License Agreement, a copy of which the Company intends to file with its quarterly report on Form 10-Q for the period ending September 30, 2014, requesting confidential treatment of certain portions.

Item 7.01 Regulation FD Disclosure

The press release dated August 4, 2014 announcing the License Agreement is attached hereto as Exhibit 99.1.

A slide presentation that will be used by management of the Company in describing the License Agreement, plans for RXDX-103 and RXDX-104 and related matters, in a webcast conference call to be held on August 5, 2014 and in later meetings, is attached hereto as Exhibit 99.2.

The information contained in this Item 7.01 and in Exhibits 99.1 and 99.2 of this Current Report on Form 8-K shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange

Act), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

| Exhibit No. | Description |
|-------------|--|
| 99.1 | Press release dated August 4, 2014. |
| 99.2 | Slide presentation dated August 5, 2014. |

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: August 4, 2014

IGNYTA, INC.

By: /s/ Jonathan E. Lim, M.D.

Name: Jonathan E. Lim, M.D.

Title: President and Chief Executive Officer

EXHIBIT INDEX

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